



norden

Nordic Innovation Centre

POSITION PAPER

CEN/STAR Trends Analysis workshop in co-operation with Nordic Innovation Centre

**Chemical and Environmental Sampling ---
Quality through Accreditation, Certification and Industrial
Standards**

April 14-15, 2005, Brussels

Executive Summary

In the CEN/STAR Trends Analysis workshop on Sampling, initiated by request of Nordic Innovation Centre, specially invited experts provided presentations on demands from regulation on sampling quality, sampling standard developments, quality assurance systems and practical experience from different sampling situations and cases. The workshop arrived at recommendations on the importance of proper sampling for environmental and product control purposes, especially to support European Regulations, trade agreements and monitoring of environment. Sampling is an integrated part of the whole measurement process and should therefore be considered especially from the viewpoint of the end-user of the results. There is a need for raising quality control issues in sampling and for the establishment of a European more uniformly co-ordinated quality system for sampling. With standard methods available, there are in principle two different ways of achieving third party assessment of the sampling protocols and procedures: accreditation of sampling organisations based upon international, national, or in-house standards and methods, and certification of individual samplers' competences for sampling. Several activities or efforts as well as research and standardisation needs for raising the quality issues in sampling were identified and presented in a position paper of the workshop.

The importance of sampling

There is a growing awareness for environmental issues in all Europe, especially in the new EU countries. It can also be clearly seen that the "quality of measurements" is emphasised in several Directives and Regulations concerning environmental issues like water quality, waste and emissions. The development of common European standards in the 1990's has made it possible to focus today more on quality aspects.

The quality of the whole measurement process should be fit for purpose. Two main aspects are uncertainty and cost. It is clear that sampling plays a key role there, in combination and in coherence with the other measurement steps. Consequently sampling should be considered in view of the entire measurement process, especially from the viewpoint of the end-user of the results.

Sampling is the first activity of testing materials. This phase of the measurement is frequently undervalued and done by less educated personal, but it contributes nevertheless very significantly to the overall accuracy of the outcome of an analysis. Irrespective of the laboratory methods used, the overall precision and accuracy of the final analytical results can be no better than the uncertainty associated with the sampling, sample storage and handling.

Sampling is a significant source of uncertainty in most test results. Often, uncertainty arising from field sampling is much greater than errors associated in sample preparation, handling and analytical and data analysis. A majority of resources in sampling studies has been devoted to assessing and to mitigating laboratory errors. This is perhaps because they have been the easiest to identify and control (e.g. through replicate analysis). As errors associated with analytical testing have been reduced, controlling sampling error is often the limiting step in assuring quality. This is particularly the case with wastes where there is often considerable variation in the nature of feedstock, producing a product that may be variable in both time and space. Understanding the variability is central to establishing appropriate sampling methods and attaching better confidence to the test results obtained. Uncertainty and sampling are key elements in all testing activities and their importance is often neglected in education and training.

Demands for improved quality in sampling and measurements are stipulated especially in

- EU Directives and common European standards
- trade agreements
- monitoring activities of quality of life.

Moreover, the traceability of measurement results is required e.g. in ISO/IEC 17025.

Directives

Quality requirement on sampling are for example mentioned in the following Regulations:

- According to Annex II pursuant to the Landfill Directive 1999/31/EC, waste sampling and testing shall be carried out by independent and qualified persons and institutions. The sampling may be carried out by producers of waste or operators under the condition that supervision of independent and qualified persons or institutions ensures that the objectives set out in the decision are achieved.
- The Directives for waste incineration 2000/76/EC and for large combustion plants 2001/80/EC set requirements for the reliable automated emission monitoring systems (AMS) installed to the process. For example, it is required that the measurements have to be carried out representatively, CEN-standards should be used as a measurement method if they are available, and, for the first time, limits for the measurement uncertainty of AMS are imposed as a condition of the suitability of results for regulatory purposes.

- The Reference Document on the General Principles of Monitoring - July 2003, supporting the IPPC directive 1996/61/EC suggests the use of e.g.: certification of personnel and equipment as part of quality assurance of monitoring and controlling emission limit values.

Monitoring

A wide range of environmental policies are based on the monitoring of chemical and/or biological parameters which are used to evaluate the environmental status of relevant compartments (e.g. water, soil, air) with the ultimate aim of making appropriate management decisions. The soundness of policy decisions is therefore directly related to the reliability of the environmental monitoring programmes. In the Water Framework Directive monitoring requirements respond to the needs of obtaining a comprehensive overview of the chemical and ecological status of surface water bodies and of the quantitative and chemical status of groundwater bodies.

Trade

Typically in commercial trade situations there is always a written contract between the supplier (vendor) and buyer (purchaser) on sampling and all quality related issues, including chemical composition and physical properties. All the protocols and methods are either internationally standardised (ISO or EN or else) or mutually agreed. If the difference of measurement results between the parties is smaller than the agreed maximum difference then the mean value of both parties is used as the agreed trade value of the lot. If the difference between the results by both parties is larger than mutually agreed threshold value then an independent third party comes and does all the same analyses as both parties have done. The agreed value of the lot is the mean of those that have been closest to each other. This kind of arrangement has been in use in industry for years and it seems to work for everybody's satisfaction in most cases. There again the most critical part of the complete measurement chain is a sampling system satisfying both commercial parties.

Tools

The basis of all environmental monitoring and control is documented and validated methods for sampling and analysis. An EN is a European Standard, and enjoys the highest "status" in the EU. EN standards find the best compromise between Consensus, Urgency, Quality and Status. A very important aspect is that when an EN is adopted in the CEN system the Members of CEN are forced to withdraw any conflicting national standard. Internationally, the corresponding system is ISO standards that are mainly followed in international trade.

Additionally there are many sectorial standards, e.g. food, feed, environment etc. and industrial branch standards, e.g. automotive, steel, coal, oil, paper, cement etc. that may cover sampling issues and protocols much more in detail than any of the above mentioned European or international standards.

With standard methods available, there are in principle two different ways of achieving third party assessment of your sampling protocols and procedures: accreditation of sampling organisations based upon international, national, or in-house standards and methods, and certification of individual samplers competences for sampling. In some cases, especially in trade, industrial standards are used to obtain more uniform sampling protocols and samples without third party assessment. Also Article 31 in the draft directive on services in the internal market calls for quality assessment provisions.

The differences between the two systems are as follows:

1. Accreditation. Sampling is part of the conformity assessment exercise, and as such, accreditation of sampling is foreseen under different accreditation standards - ISO/IEC 17025 (laboratories), ISO/IEC 17020 (inspection bodies) and ISO 15189 (medical laboratories). An organisation can be accredited to perform a service such as sampling and chemical analyses if the requirements laid down in the above mentioned standards are fulfilled by the organisation, and thus demonstrate the competence to perform such activities. Examples of the requirements are preparation of a detailed quality manual, validated procedures for performance of analysis and sampling, quality assurance and control, documentation, training and qualifications of personnel, appropriate equipment and traceable on-site measurements. Accreditation is granted and periodically controlled by an independent third body, i.e. the national accreditation body. Accreditations can achieve worldwide recognition through the multilateral recognition agreements between accreditation bodies. Accreditation provides the highest level of competence assurance.
2. Certification. A sampler can have the competence for sampling certified according to a certification scheme leading to the issue of a certificate of sampling competence, including periodic surveillance of maintenance of the competence. The certification scheme can add requirements for methods, equipment, documentation and quality control. The requirements of sampler certification are set in the ISO/IEC 17024 standard: Conformity assessment - General requirements for bodies operating certification of persons.

Each of the above two options have their positive and negative points and the organisation in charge of sampling should choose the option that best suits their own demands and organisational structures and best satisfies the customer needs. One should also bear in mind that additional quality systems and audits or changes in them are not cheap for an organisation. Hence the customer point of view should be stressed more than own desire.

Accreditation is probably the best option for laboratories having already accreditation for the analytical parts of their operation. Accreditation guarantees technical competence. Accreditation is also well-known among the laboratory community and their customers. A major drawback is the requirement for verification of sampling traceability inherent in ISO/IEC 17025 that may be difficult to fulfil due to a very limited availability of sampling intercomparisons/proficiency tests and sampling reference sites (equivalent to certified reference material used in chemical analysis). The data base EPTIS (www.eptis.bam.de/) lists some 14 proficiency tests where sampling is mentioned and some of them are genuine sampling comparisons. The costs and the administrative burden of accreditation will be large for organisations not already accredited for other purposes such as e.g.: accredited analytical laboratories.

Certification of individual samplers, would probably be the best solution for samplers operating independently or as part of a non-accredited organisation such as many consultancy companies. However, traceability and technical competence is not guaranteed by certification. Costs and administrative burdens would be more realistic than accreditation for these samplers. Simple personnel certification following ISO/IEC 17024 does not include assessment of methods, equipment, documentation and quality control. This may lead to reduced comparability and traceability of certified sampling and such requirements should be added. The need for sampler intercomparisons and sampling reference sites with a certified sampler is similar to that in an accredited organisation. Finally, certification of sampler competence may be part of the documentation of personnel education and competence required for accreditation.

The agreed use of industrial standards without third party assessment is probably the most common practice in industry today. It is fit for industrial purposes but problems may arise when comparing the results between various plants and industries nationally and internationally. There are also huge financial impacts here because of worldwide emission trade coming soon to reality. The total financial impact of emission trade is estimated to be of the order of several tens of billions of euros.

Recommendations

The workshop was initiated by request of Nordic Innovation Centre. The objective was to:

- *Highlight and emphasise importance of proper sampling for environmental or chemical purposes*
- *Present improved and potential quality control procedures to fulfil future needs of European Regulations and to achieve good and reliable sampling needed for monitoring*
- *Promote actions to improve the reliability of sampling and support the initiation of sampling proficiency test (and hence measurement) for fulfilling European Regulations and to overcome challenges of international trade*
- *Review and exchange experience and know-how arising from different areas of sampling*
- *Confirm the needs for standards, with sufficient details, and detect needs for further research including uncertainty of sampling*

Specially invited experts provided presentations on a number of aspects to be taken in consideration for proving quality in sampling. A representative from EU's DG Environment highlighted monitoring policy requirements in environmental Directives and their links to standardisation, and expert speakers from industry, research institutes, standardisation and accreditation bodies presented the state of the art, standard developments and future outlooks in different sampling situations and cases (soil, waste, sediment, biowaste, sludge, compost, waste water, air emissions).

The workshop arrived at following recommendations on sampling in environmental measurement on liquid, sludge and solid materials:

- *to prevent, reduce and mitigate adverse ecological, economical, safety and health effects caused by improper and inadequate sampling not fit for the purpose, the workshop strongly advise European countries to:*
1. Acknowledge sampling as part of the whole measurement process and consequently the importance of proper sampling for environmental and product control purposes, especially to support European Regulations, trade agreements and monitoring of environment.
 2. Actively support the establishment, preferably by the European Commission, of a forum for regulators, sampling experts, representatives from standardisation organisations and accreditation bodies for exchange of views and opinions on means and measures of future Directives.
 3. Support efforts for raising the quality control issues needed to be taken into account in various sampling situations.
 4. Assist in the establishment of a European more uniformly co-ordinated quality system for sampling in the most important environmental measurements.
 5. Facilitate, support and fund the development of horizontal sampling standards especially for common sampling situations and also validation of sampling standards for most important environmental measurements.
 6. Recommend that a uniform approach for personnel certification of samplers is designed for the EU, so that the system can develop and gain more acceptance.
 7. Recommend that Accreditation Bodies be encouraged to work together with interested parties to increase the confidence of accredited sampling protocol.
 8. Assist and support the development of tools to assure traceability and comparability of sampling such as e.g.: sampler/sampling intercomparisons and sampling reference sites.
 9. Support and facilitate transfer and exchange of information to all EU member states on available standards and concepts for quality management in sampling.

TABLE: Comparison of various quality assurance systems in sampling.

System	Benefits	Drawback	Typical examples	Research /standardisation needs
Third party assessment by accreditation	<ul style="list-style-type: none"> - third party assessment of sampling organisation with technical competence proved (via audits) - international recognition of competence thanks to multilateral agreements signed between accreditation bodies in Europe and throughout the world - proved education of personnel - comparability and traceability demonstrated, when possible - experience from participation in sampling inter-comparisons (when possible) 	<ul style="list-style-type: none"> - expensive for organisations with small number of samplers - need for standard procedures for sampling - sampling intercomparison and reference sites not always available - required competence (training and maintenance) not defined - need periodic auditing in the field of the sampling step in view of the whole measurement - need for in house validation for in house methods 	<ul style="list-style-type: none"> - laboratories involved in sampling (e.g. water analysis) - stack emission measurement - in some countries inspection bodies examining suspected or contaminated areas to judge or recommend solutions / actions 	<ul style="list-style-type: none"> - need for common recommendations / concepts for quality control - validation of sampling methods - establishment of proficiency testing schemes - establishment of sampling reference sites - need for a flexible approach in development of sampling standards - needs of standards dedicated to sampling scenarios of interest, especially horizontal standards when possible
Third party assessment by personnel certification	<ul style="list-style-type: none"> - third party assessment of sampler competence - low costs for organisations and companies without an accreditation or a certified quality system - international recognition of conformity with internationally based certification schemes - proved, defined and uniform education of personnel 	<ul style="list-style-type: none"> - comparability and traceability not demonstrated - third party assessment limited to individual sampler with technical competence not proved - need for standard procedures for sampling - assessment limited to individual persons as samplers. - no assessment of the organisation - scope of the assessment varying between certification scheme - no quality management system required for the organisation 	<ul style="list-style-type: none"> - monitoring of environment by authorities - industry performing self control - product control in trade industry and services - consultants performing site investigations 	<ul style="list-style-type: none"> - development of common personnel certification schemes - recommendations / concepts for quality control and training courses - validation of sampling methods - establishment of proficiency testing schemes - establishment of sampling reference sites - needs of standards dedicated to sampling scenarios of interest, especially horizontal standards when possible
Self assessment on sampling standards	<ul style="list-style-type: none"> - flexibility - regular, self motivated update to keep methods at "state of the art" - requirements and validated testing methods available 	<ul style="list-style-type: none"> - no third party assessment - not possible at this stage to suggest a single sampling strategy for all materials - standards are voluntary - matrix and purpose specific applicability of standards not always clear - no quality management system required for the organisation - comparability and traceability depends heavily on the internal procedures of the laboratory and on its reputation 	<ul style="list-style-type: none"> - trade and industry - services - research activities - process control 	<ul style="list-style-type: none"> - guidelines needed for (proper) use of standards, sampler intercomparisons and sampling and validation of reference sites - need for product based standards - needs of standards dedicated to sampling scenarios of interest, especially horizontal standards when possible - validation of sampling methods together with the validation of other measurements